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Original article

Novel driveline route for prevention from driveline infection: Triple tunnel method

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ABSTRACT

Background: The most prevalent and serious infection related to left ventricular assist devices (LVADs) is driveline infection (DLI). From 2014, we employed a revised surgical technique (triple tunnel method), which deployed a longer subfascial driveline (DL) route.
Methods and patients: We retrospectively analyzed 34 patients fitted with either of the two types of axial pumps: HeartMate II ($n = 23$) and Jarvik 2000 ($n = 11$). Prior to 2014, the DL proceeded from the pump pocket just above the posterior sheath of the rectus muscle toward a vertical skin incision at the right lateral border of the rectus muscle. Then, DL was turned leftward into the subcutaneous tissue to redirect its exit to the left side [subcutaneous tissue group (Group S): $n = 14$]. From 2014, we made an additional skin incision below the umbilicus with the aim of lengthening the subfascial DL route [muscle group (Group M): $n = 20$].
Results: DLI occurred in 10 patients (71.4%) in Group S and in 1 patient (5%) in Group M ($p < 0.05$, Chi-square test). The freedom rate from re-admission at 1 year due to DLI was 64% in Group S and 95% in Group M, respectively ($p = 0.021$, log-rank test). Furthermore, logistic regression analysis revealed that DL route was significantly associated with DLI (odds ratio, 10.1; 95% confidence interval, 1.15–275.3).
Conclusion: Although a longer follow-up period will be needed, the triple tunnel method may be beneficial in the prevention of DLI.
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Background

The successful clinical introduction of left ventricular assist devices (LVAD) has led to considerable changes in the management of end-stage heart failure. Moreover, the focus of LVAD infections has progressively shifted from the perioperative period toward late-onset infections [1]. Device-related infections are among the most commonly occurring serious adverse events, with a reported incidence of 0.34 events per patient-year (19%) in bridge-to-transplant (BTT) patients and 0.48 events per patient-year (35%) in destination therapy patients [2]. Such infections are also a leading cause of rehospitalization, which increases the overall costs associated with LVAD therapy. The three main LVAD components at risk of infections are the driveline (DL), the pump and its surrounding pocket, and the internal (blood-containing) flow tract. Among these three components, DL is known to be most susceptible to infection at the site where it exits the body surface. In fact, with the present devices available in clinical practice, this specific region has become the real Achilles' heel of long-term LVAD therapy [1]. Because surgical revision of infection at the DL exit site remains challenging [3], a longer DL route is a good option to prevent DL infection. Therefore, we have employed the longer subcutaneous DL route, and since 2014, we further modified this longer subcutaneous DL route, which includes a longer subfascial DL route named triple tunnel method. In the present paper, we aimed at comparing the two treatment options; longer subcutaneous DL route and longer subfascial DL route.

Materials and methods

All subjects enrolled in this research have given their informed consent. This retrospective review includes 82 consecutive BTT patients between April 2011 and July 2015 who were implanted

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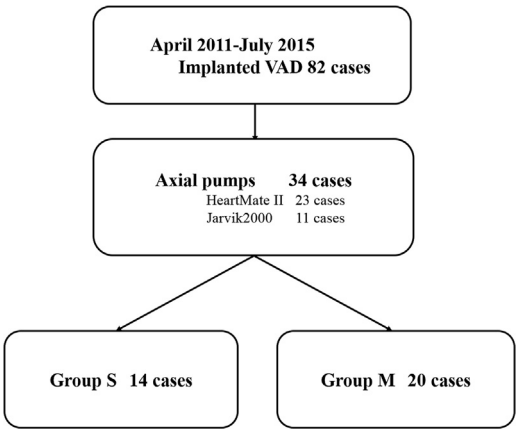

Fig. 1. Flowchart describing the overall experimental design. VAD, ventricular assist device; Group S, subcutaneous tissue group; Group M, muscle group.

with LVADs at The University of Tokyo Hospital. Among these, we analyzed 34 patients fitted with axial pumps: 23 patients implanted with HeartMate II pump (Abbott Laboratories, Chicago, IL, USA) and 11 patients implanted with Jarvik 2000 (Jarvik Heart Inc., New York, NY, USA) pump (Fig. 1). In this study, Evaheart (Evaheart, Inc., Houston, TX, USA) and DuraHeart (Terumo, Tokyo, Japan) cases were excluded due to larger DLs compared with HeartMate II and Jarvik 2000. For each patient, dressings on the DL exit site were daily changed in a sterile fashion. Furthermore, DL was immobilized by an anchor or binder in order to prevent mechanical trauma at the exit site.

Definition of DL infection

DL infection (DLI) was diagnosed according to the criteria of the International Society of Heart and Lung Transplantation consensus such as clinical evidence of infection, such as redness, swelling, pain, fever, fluid discharge, or leukocytosis associated with a positive culture from the skin and/or tissue surrounding DL [4]. Additionally DLI in this study was defined as patients who needed re-admission for treatment by intravenous antimicrobial therapy or debridement.

Daily exit site wound care and culture protocol

Daily exit sites cleansing in our institute was described elsewhere [5,6]. Briefly, it was performed every day by patients or medical staff in a sterile fashion using diluted hydrogen peroxide and placement of an anti-micro viral occlusive dressing. Routine cultures from exit sites were performed once a week, and additional cultures were collected as needed.

Subcutaneous group (Group S)

Prior to 2014, DL proceeded from the pump pocket just above the posterior sheath of rectus muscle toward a vertical skin incision at the right lateral border of the rectus muscle. Then, DL was turned leftward into the subcutaneous tissue to redirect its exit to the left side (Fig. 2).

Muscle group (Group M): triple tunnel method

Since 2014, we have been making an additional skin incision below the umbilicus with the aim of lengthening the subfascial route of DL. As shown in Fig. 2, DL was turned leftward into the subfascial layer of the rectus muscle to redirect its exit to the left side via a small incision in the median lower abdomen.

Data analysis

All statistical analyses were performed using JMP 11 (SAS Institute Inc., Cary, NC, USA). All variables are expressed as mean ± standard deviation. The Chi-square test was used to compare categorical variables for univariate analysis. Postoperative freedom-from-event curves were generated using the Kaplan–Meier method. Statistical significance was considered when $p < 0.05$. Clinical outcome about DLI was measured at 1 year.

Results

Patient demographics are shown in Table 1. In total, there were 14 patients in Group S with a mean age of 31.7 ± 12.0 years (range, 16–53 years) and 20 patients in Group M with a mean age of 32.3 ± 12.0 years (range, 11–58 years). All patients were retrospectively analyzed. Mean follow-up period was 521 ± 260.3 days

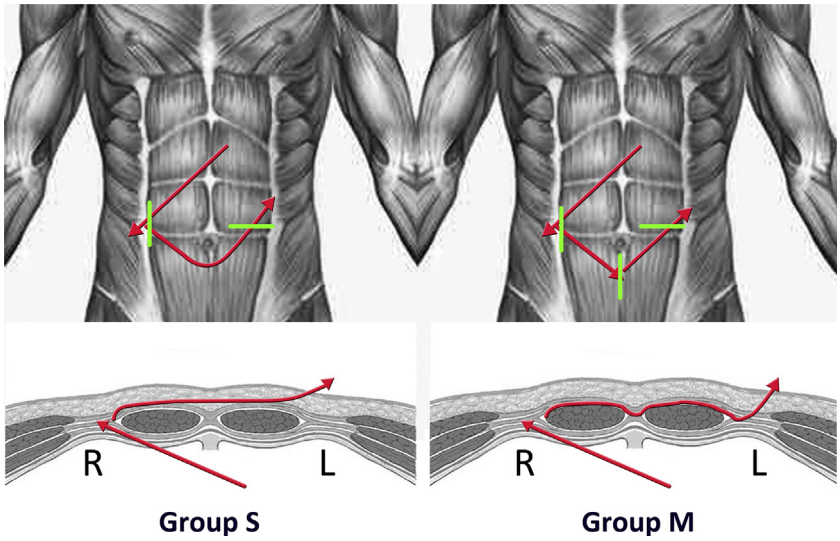

Fig. 2. A schematic course of the driveline route of Group S and Group M showing that longer C-shaped subcutaneous and subfascial courses were provided. Group S, subcutaneous tissue group; Group M, muscle group.

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